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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,563	08/29/2000	Tongtong Wang	210121.478C10	1478

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/19/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/651,563

Applicant(s)

Wang et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 3, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 11-68 is/are pending in the application.
- 4a) Of the above, claim(s) 1-3, 11-60, and 63-65 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 61 is/are allowed.
- 6) ☒ Claim(s) 62 and 66-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Amendment filed 05/03/02 is acknowledged. Claims 4-10, which have been under examination, are canceled. Claims 61-68 are added. Claims 1-3, 11-68 are pending.

Newly submitted claims 63-65 are directed to an invention that is patentably distinct from the invention originally claimed. Claims 63-65 are drawn to polynucleotides having different length, from 50-mers to 100-mers, to 400-mers. There is no common core structure for the polynucleotides as claimed. Accordingly, a reference teaching, e.g., a polynucleotide comprising a 50-mer from a certain parent polynucleotide, will not teach or suggest polynucleotides comprising , e.g., 100-mer from the same parent polynucleotide. Therefore, each group requires non co-extensive sequence and literature searches. The inventions are drawn to independent and/or patentably distinct polynucleotides since each would be expected to possess distinctly different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 63-65 are

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withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 63-65 are withdrawn, and claims 1-3, 11-60 remain withdrawn from further consideration. Cancellation of claims 1-3, 11-60, 63-65 is requested. Also, amendment of claims 66,67 to read on the elected subject matter is requested.

Claim Rejections - 35 USC § 112, second paragraph.

3. Claims 62,66 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims are drawn to products which can be used in the diagnostics of any cancer, while the specification discusses only lung cancer. The scope of the term "cancer" is not identified.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 62,66,67,68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides or derivatives thereof which can be used in diagnostics of lung cancer, does not reasonably provide enablement for other polynucleotides (e.g., having certain % identity) which can be used in diagnostics of any other type of cancer. Specification discusses procedures allowing to reveal whether a polynucleotide is overexpressed in lung tumor tissues. No other tumorous tissue type and related essays are discussed. Accordingly, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

5. Claims 62,66-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides having at least 90% degree of identity with SEQ ID NO: 808, wherein the polynucleotides can be used in the detection of cancer. The specification discloses SEQ ID NO: 808 which corresponds to the cDNA encoding protein SEQ ID NO: 69 (referred to as L552S), and is overexpressed in lung

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tumor tissue. Polynucleotide SEQ ID No. 808 itself meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claim 62 is drawn to nucleotide sequences having more than 90% identity to the elected SEQ ID 808, does not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. Applicant is advised that absent factual evidence, a percentage sequence similarity of less than 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. The effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not. Therefore, sequence similarity result in an unpredictable and therefore unreliable correspondence between the newly discovered sequence and a similar biomolecule of known function or expression. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be useful in the detection of cancer are present in the specification. With the exception of SEQ ID NO: 808, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. The species specifically disclosed are not representative of the genus because the genus is highly variant. Adequate written description requires more than a mere

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statement that it is part of the invention and reference to a potential method for isolating it. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. Accordingly, the specification does not provide a written description of the invention of claim 62, and, consequently, of its complement, expression cell and vector of claims 66-68. Note, that even though specification indicates that SEQ ID NO: 808 contains open reading frame encoding protein SEQ ID NO: 69, the claims are not drawn to polynucleotides encoding a particular protein. The specification provides insufficient written description to support the genus encompassed by the claim.

Therefore, only SEQ ID NO: 808 but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph.

Conclusion.

6. Claim 61 is allowed.
7. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

July 12, 2002

